

**REMARKS**

Claims 1, 3-6, 9-12, 22, 25-26 are pending. Claims 1, 3-6, 9-12, 22, and 25-26 have been amended without prejudice or disclaimer with respect to the underlying subject matter. Claims 2, 7-8, 13-21, 23-24, and 27-72 have been canceled without prejudice or disclaimer. Support for the foregoing amendment can be found throughout the Specification and claims as originally filed, for example, at page 4, lines 10-23; page 11, lines 13-20; page 13, lines 5-9; page 17, line 27 - page 21, line 20; and page 32, line 9 - page 33, line 15. No new matter enters by way of the foregoing amendment. Applicants also note the Office's assertion that Claims 39-72 are drawn to different inventions and will not be examined in the present application. Office Action at page 2.

**I. Objection to the Specification**

The claims stand objected by the Office for "reciting non-elected species." Office Action at page 2. As set forth in the response mailed November 14, 2008, Applicants provisionally elected Species B within Group I, drawn to suppression of expression of FAD2 and increase in expression of beta-ketoacyl-ACP synthase IV. Consistent with MPEP § 809.02(a), Applicants note that "[u]pon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141."

**II. Rejection under 35 U.S.C. § 112, First Paragraph, Enablement**

Claims 1-6, 9-12, 22, 23, 25, and 26 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the Specification in such a way so as to enable those skilled in the art to make and/or use the invention commensurate in scope with the claims. Office Action at page 2. In rejecting the claims, the Office asserts that given the high level of unpredictability, the lack of working examples, and the absence of guidance with regard to choosing from a multitude of constructs to produce and select for the claimed soybean seeds, one of skill in the art would have to undergo undue experimentation in order to make and use the invention in a manner that is commensurate in scope with the claims. *Id.* at pages 4 and 5.

Applicants respectfully disagree with the Office's rejections under 35 U.S.C. § 112, second paragraph. However, solely in order to facilitate prosecution, Applicants have amended the claims without prejudice or disclaimer. As such, Applicants respectfully assert that the claim rejections are rendered moot.

At the outset, Applicants strongly disagree with the Office's assertion that "the specification does not disclose any soybean seeds having the claimed ranges of fatty acids prepared by any method." Office Action at page 3. This assertion is in no way reflective of the breadth provided. The Specification as well as data from post-filed co-pending application U.S. Application Serial No. 11/376,328 provide for numerous soybean seeds with fatty acid compositions within levels of the claimed invention. See, for example, U.S. Application Serial No. 11/376,328 Specification at Tables 8-20; 25; and 26. For example, as described in U.S. Application Serial No. 11/376,328, pMON68539, pMON95829, pMON93505, pMON93506, pMON93501, pMON97552, pMON93758, pMON97553, pMON93770, pMON93759, pMON97554, pMON93771, pMON97555, pMON97562, and pMON97563 are capable of producing seeds exhibiting an oil composition comprising 55 to 80% by weight oleic acid and 2 to 8% by weight saturated fatty acids.

Moreover, without being limited, data from post-filed co-pending U.S. Application Serial No. 11/376,328 further confirms soybean lines transformed with a pMON93501 construct are capable of exhibiting fatty acid profiles comprising 55 to 80% by weight oleic acid and 2 to 8% by weight saturated fatty acids. U.S. Application Serial No. 11/376,328 Specification, for example, at page 118, line 17 - page 119, line 25; Example 14; and Table 12. pMON93501 having a *FAD2-1A* intron, KAS IV gene, and delta-9 desaturase gene. U.S. Application Serial No. 11/376,328 Specification, for example, at page 82, line 21 - page 83, line 2. Given this, one of ordinary skill in the art at the time the invention was made would have the ability to practice the claimed invention in a manner that is commensurate in scope with the claims without undue experimentation.

Applicants disagree with the Office's reliance on De Luca *et al.* (*AgBiotech News and Information* Vol. 5 No. 6 :255N-229N, 2002) ("De Luca") to allegedly demonstrate the unpredictability of the art. Office Action at page 3. At best, De Luca only provides general teachings of unpredictability unrelated to the claimed invention. De Luca ascribes the alleged

unpredictability to “our poor understanding of plant metabolic pathways and their *in vivo* regulation” (see the paragraph bridging the columns on page 225N). The Office does not suggest that there is a poor understanding of fatty acid biosynthesis or its *in vivo* regulation. Instead, De Luca reports of “spectacular results” (see the last paragraph on page 228N) and cites a successful example of altering plant fatty acid biosynthesis (see first full paragraph of 228N). Moreover, De Luca, published in 1993, is not an appropriate reference to determine the state of the art when the instant application was first filed in March 21, 2002. Given this, one of skill in the art at the time the invention was made would not question the enablement of the claimed invention on the basis of De Luca.

Applicants further disagree with the Office’s reliance on Voelker *et al.* (*Annual Review of Plant Physiology and Plant Molecular Biology*, 52: 335-361, 2001) (“Voelker”) to allegedly show that the claims are not enabled. Office Action at pages 3-5. In rejecting the claims, the Office asserts that Voelker “teach that there are many hundreds of different fatty acids found in natural plant oils that are mostly produced as a result of changes in a few amino acids of a handful of lipid biosynthetic genes and that plants transformed with fatty acid biosynthesis genes from heterologous plant species do not always have fatty acid profiles that correspond to those of the plant from which the gene was cloned.” *Id.* (citations omitted). This is inapplicable when the claimed invention is not reciting a new fatty acid in soybean or a fatty acid composition yet to be demonstrated. Instead, Applicants have claimed a fatty acid profile consistent with that of plants produced by Applicants according to the specification.

The Office further asserts that Voelker “teaches that the hydroxylase enzyme from *Lesquerella* is bifunctional in that it has some omega-6 desaturase activity in addition to hydroxylase activity and that small differences in active site geometry are responsible for the different functional activities. There are also FAD2 related sequences that function as epoxigenases and acetylenases.” *Id.* (citations omitted). Applicants fail to understand the Office’s reliance on active site geometry, change in substrate specificity, and FAD2 functions to allegedly show that the claims are not enabled when the claims are directed to a soybean with a genome that silences *endogenous* FAD2.

Even assuming, *arguendo*, that these statements are true, the Office has misapplied Voelker’s teaching of “unpredictability” to the present invention. The Office appears to use

Voelker to allege the unpredictability of the resultant seed fatty acid composition in transformed seeds and plants. In rejecting the claims, the Office asserts that Voelker “teach the complexity of plant lipid biosynthesis and the uncertainty of the resultant seed fatty acid composition when transforming plant species with heterologous genes.” *Id.* at page 3. The Office further asserts that Voelker “also teach the uncertainty with regard to the distribution membrane and storage lipids in plants transformed with heterologous fatty acid biosynthesis genes.” *Id.* at page 4. However, Applicants are not claiming the method by which the invention was created; rather, the claims are directed to compositions. Here, Applicants are claiming compositions, namely, soybean seeds transformed with nucleic acid molecules including a genome with nucleic acid sequences that suppress the expression of endogenous soybean *FAD2-1A* and increase the expression of KAS IV, and such plants were achieved by the Applicants. Given this, one of skill in the art would not interpret Voelker in such a manner that would shed doubt on the enablement of the claimed invention.

Given the disclosure, Applicants respectfully submit that one of ordinary skill in the art would have the requisite skill to create a construct having a nucleic acid sequence that suppresses the expression of endogenous soybean *FAD2-1A* and increases the expression of KAS IV, and to transform the construct into a soybean seed, where the seed exhibits an oil composition comprising 55 - 80% by weight of oleic acid and 2 to 8% by weight saturated fatty acids. Applicants have sufficiently described the claimed invention such that one of skill in the art in light of the specification would be able to practice the invention commensurate in scope with the claims. In sum, such disclosure provides adequate direction, including working examples, to teach the skilled artisan how to make and use the claimed invention without undue experimentation.

It is submitted that Applicants have provided considerable direction and guidance, and have presented working examples such that it is well within the level of ordinary skill in the art to practice the invention without undue experimentation. The Office has not provided sufficient evidence to discredit the teaching in the specification. Rather, the Office suggests inapplicable and generalized observations.

Accordingly, for at least these reasons, it is submitted that the claims are sufficiently enabled under 35 U.S.C. § 112, first paragraph, and withdrawal of this rejection is respectfully requested.

### **III. Rejections under 35 U.S.C. § 102**

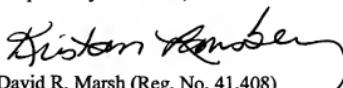
Claims 1, 9, and 10 stand rejected under 35 U.S.C. § 102 as allegedly being anticipated U.S. Patent 5,714,670 (Fehr *et al.*). Office Action at page 5.

Applicants respectfully disagree with the rejection under 35 U.S.C. § 102. However, Applicants believe that this rejection has been rendered moot by the foregoing claim amendments. As such, Applicants respectfully request withdrawal of this rejection.

### **CONCLUSION**

In view of the above, each of the presently pending claims is believed to be in immediate condition for allowance. Accordingly, the Office is respectfully requested to withdraw the outstanding objection and rejections of the claims, and to pass this application to issue. The Office is encouraged to contact the undersigned at (202) 942-5186 should any additional information be necessary for allowance.

Respectfully submitted,



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